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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,657	02/19/1999	PETER RUHDAL JENSEN	55411.000002	1335

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EXAMINER

MCGILLEM, LAURA L

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/242,657	Applicant(s) JENSEN ET AL.	
	Examiner Laura McGillem	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

It is noted that Applicants have filed an After Final amendment on 4/24/2006 canceling claims 1-15, 17-21 and 23-27. The amendment has been entered. In the previous Office action, mailed 12/23/2005, claims 16 and 22 were indicated as allowable. However, on further consideration of the prior art, a new ground(s) of rejection is made in view of Oliphant and Struhl (of record).

Claim Objections

Claim 16 is objected to because of the following informalities: it is grammatically incorrect in section 16 (i)(b) line 2 because there is not a verb between the words "sequences" and "a TATA-box". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite because it recites the phrase "set of promoter sequences covering a range of promoter activities" and it is not clear how sequences can "cover" a range of activities. It may be remedial to amend the claim to include the

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phrase --with respect to promoter strength-- as is disclosed on page 10a (lines 6-7) of the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Oliphant and Struhl (of record).

The disclosure does not provide a specific definition of “at least half” in the context of the phrase “at least half of each of the consensus sequences”. Therefore, the claim limitation can be interpreted that any permutation of the consensus sequence having 50% identity with one of the consensus sequences comprises “at least half”

Oliphant and Struhl teach a method of making a large collection of hybrid *E.coli* promoter elements. Oliphant and Struhl use a method of random selection in which a sequence of random DNA replaces a wild-type element in order to generate many different sequences with specific functions (see page 7674, Figure 1 and 2nd paragraph). Oliphant and Struhl teach that a sequence comprising functional -10 and -35 promoter elements determined to be consensus sequences in naturally occurring promoter elements were subject to random selection. Oliphant and Struhl teach that oligonucleotides were synthesized using a mixture of all 4 nucleotides, producing

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oligonucleotides of random sequence and heterogeneous length, which were then converted to double stranded DNA. Oliphant and Struhl teach that the DNA was cloned into phage libraries and operably linked to a *his3* gene encoding an enzyme that allows *E.coli* to grow in the absence of histidine (imidazolglycerolphosphate dehydrogenase) (see page 7675, 2nd and 3rd paragraph, in particular).

Oliphant and Struhl teach that *E.coli* containing the randomly selected promoter elements linked to IGP dehydrogenase were challenged with aminotriazole, a competitive inhibitor of IGP dehydrogenase. The level of IGP dehydrogenase expression in the cells impacted the viability of the *E.coli* in the presence of aminotriazole, and the promoter elements were ranked according to their levels of function (i.e. the ability to promote sufficient expression of (IGP) dehydrogenase for growth in restricted conditions) (see page 7678, 4th and 5th paragraph, in particular). Oliphant and Struhl teach the variation of sequences flanking each of the consensus sequences (see page 7674, Figure 1, page 7677, Figure 3, and Page 7679, in particular). Further, Oliphant and Struhl disclose that their results for random promoter elements agreed with wild-type promoter structure such that the most frequently occurring nucleotides in wild-type *E.coli* promoters are **TTGACA** (-35 element) and **TATAAT**(-10 element) with the most highly conserved positions in the -35 element being the first three nucleotides (in bold) and the most highly conserved element in the -10 element being the first two and the last positions (see page 7680, 2nd paragraph), which reads on DNA sequences each comprising at least half of each of the consensus

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sequences of a prokaryotic microorganism wherein at least one of the consensus sequences is TATAAT and at least one is TTGACA.

Conclusion


Claim 22 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
5/5/2006


DANIEL M. SULLIVAN
PATENT EXAMINER